



BioDelivery Sciences Announces the Granting of Two New Patents to be Listed in FDA's Orange Book Further Extending and Strengthening Patent Protection on BELBUCA®, BUNAVAIL® and ONSOLIS®

March 31, 2017

RALEIGH, N.C., March 31, 2017 /PRNewswire/ -- BioDelivery Sciences International, Inc. (NASDAQ: BDSI) announced that two important new patents were granted extending patent protection around all three of its FDA approved products, BELBUCA® (buprenorphine) buccal film, BUNAVAIL® (buprenorphine and naloxone) buccal film, and ONSOLIS® (fentanyl buccal soluble film), further strengthening BDSI's overall intellectual property position.

In a patent application (US Patent Application Serial No. 15/212,912) covering the composition of the BioErodible MucoAdhesive (BEMA®) drug delivery technology, which is the basis for BELBUCA and BUNAVAIL, a Notice of Allowance was issued providing additional patent coverage for BELBUCA and BUNAVAIL to July 2027. This patent will be listed in the Orange Book.



Additionally, a patent (US Patent No. 9,597,288) was issued on March 21, 2017, which extends patent protection on ONSOLIS from January 2020 to July 2027. This patent will also be listed in the Orange Book. The U.S. rights to ONSOLIS are licensed to Collegium Pharmaceutical. Under the terms of BDSI's licensing agreement for ONSOLIS with Collegium, the patent grant is associated with a \$3 million milestone payment to BDSI, the payment of which is due upon U.S. Food and Drug Administration (FDA) approval of a supplemental application supporting the new manufacturer for ONSOLIS. This, along with a \$4 million milestone payment tied to the first commercial sale of ONSOLIS, are anticipated in the first half of 2018. Under the terms of the agreement with our former U.S. partner, Meda, the milestones and future royalties to BDSI will be shared between BDSI and Meda.

About BioDelivery Sciences International

BioDelivery Sciences International, Inc. (NASDAQ: BDSI) is a specialty pharmaceutical company with a focus in the areas of pain management and addiction medicine. BDSI is utilizing its novel and proprietary BioErodible MucoAdhesive (BEMA®) technology and other drug delivery technologies to develop and commercialize, either on its own or in partnership with third parties, new applications of proven therapies aimed at addressing important unmet medical needs.

BDSI's development strategy focuses on the utilization of the FDA's 505(b)(2) approval process. This regulatory pathway creates the potential for more timely and efficient approval of new formulations of previously approved therapeutics.

BDSI's area of focus is the development and commercialization of products in the areas of pain management and addiction. These are areas where BDSI believes its drug delivery technologies and products can best be applied to address critical unmet medical needs. BDSI's marketed products and those in development address serious and debilitating conditions such as breakthrough cancer pain, chronic pain, painful diabetic neuropathy and opioid dependence. BDSI's headquarters is in Raleigh, North Carolina.

For more information, please visit or follow us:

Internet:	www.bdsi.com
Facebook:	Facebook.com/BioDeliverySI
Twitter:	@BioDeliverySI

BUNAVAIL® (buprenorphine and naloxone) buccal film (CIII) and BELBUCA® (buprenorphine) buccal film (CIII) are marketed in the U.S. by BioDelivery Sciences. ONSOLIS® (fentanyl buccal soluble film) (CII) is licensed in the U.S. to Collegium Pharmaceutical pursuant to the U.S. licensing and development agreement between BDSI and Collegium. For full prescribing information and important safety information on BDSI products, including BOXED WARNINGS for ONSOLIS, please visit www.bdsi.com where the Company promptly posts press releases, SEC filings and other important information or contact the Company at (800) 469-0261. For full prescribing and safety information on BELBUCA, please visit www.belbuca.com and for full prescribing and safety information on BUNAVAIL, please visit www.bunavail.com.

Cautionary Note on Forward-Looking Statements

This press release and any statements of employees, representatives and partners of BioDelivery Sciences International, Inc. (the "Company") related thereto contain, or may contain, among other things, certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve significant risks and uncertainties. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, projections, expectations and intentions and other statements identified by words such as "projects," "may," "will," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans," "potential" or similar expressions. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties, including those detailed in the Company's filings with the Securities and Exchange Commission. Actual results (including, without limitation, the anticipated benefits to the Company of the new patents described herein) may differ significantly from those set forth in the forward-looking statements. These forward-looking statements involve certain risks and uncertainties that are subject to change based on various factors (many of which are beyond the Company's control). The Company undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future presentations or otherwise, except as required by applicable law.

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